

DATA EVALUATION RECORD

1. **CHEMICAL:** Tebuthiuron. Shaughnessey Number: 105501.
2. **TEST MATERIAL:** Tebuthiuron, N-[5-(1,1-dimethylehtyl)-1,3,4-thiadiazol-2-yl]-N,N'dimethylurea, 99.1% purity, colorless solid.
3. **STUDY TYPE:** Avian Dietary LC₅₀ Test.
Species tested: Bobwhite Quail (Colinus virginianus).
4. **CITATION:** Negilski, D.S. et al. 1988. The Toxicity of Tebuthiuron to Juvenile Bobwhite in a Five-Day Dietary Study. Study performed by Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, Indiana. Submitted by Elanco Products Company.
5. **REVIEWED BY:**

Tracy L. Perry Wildlife Biologist EEB/EFED	Signature: Tracy L. Perry Date: 5/29/91
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6. **APPROVED BY:**

Henry T. Craven Head, Section IV EEB/EFED	Signature: Henry T. Craven Date: 5/29/91
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7. **CONCLUSIONS:** The study is scientifically sound and fulfills the requirements for an avian dietary LC₅₀ test. With a LC₅₀ of greater than 5113 ppm, tebuthiuron is considered to be practically non-toxic to the bobwhite quail.
8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:10. DISCUSSION OF INDIVIDUAL TESTS: N/A11. MATERIALS AND METHODS:

A. Test Animals: The birds used in this study were 11-day-old bobwhite quail, ranging in weight from 22.0g to 26.6g. Bobwhite quail eggs, obtained from Barrett's Quail Farm in Houston, Texas, were hatched at the testing facility and transferred to pens for an 11-day acclimation period. During this period, chicks had free access to TEKLAD diet and Greenfield city water. A photoperiod of 24 hours of light was maintained via fluorescent bulbs. Chicks were evaluated daily for abnormal behavior or physical injury.

B. Test System: Test pens were drawer-type brooders made out of stainless steel and measuring 61 x 46 x 18 cm. The floors were plastic-coated stainless steel. Temperature ranged from 37°C to room temperature (26-28°C) with a relative humidity of 25% to 46%. Greenfield city water and TEKLAD feed were provided ad libitum. A photoperiod of 24 hours of light was maintained throughout the study.

C. Dosage: The nominal concentrations chosen for the study were 0 (control), 600, 1200, 2500, and 5000 ppm. Doses were not adjusted to 100% a.i. Test diets were analyzed for tebuthiuron concentration immediately after diet preparation. The stability and homogeneity of tebuthiuron in the avian diet were also measured.

D. Design: Two replicates of the diet control and each dietary concentration were performed. Birds were randomly assigned, regardless of sex, to one of 10 pens (5 birds per pen). Each bird was uniquely identified with a wing tag. Birds were observed at least twice daily for signs of toxicity and mortality. Individual body weights were recorded at test initiation (day 0), test day 5, and at the termination of the test (day 8). Food consumption was measured during the treatment and basal diet phases of the test (test days 5 and 8).

E. Statistics: Mean body weight, body weight gain and food consumption were statistically analyzed using Dunnett's 't' test.

12. REPORTED RESULTS:

Analyses of freshly prepared diets indicated that tebuthiuron concentrations ranged from 101% to 105% of

nominal concentrations. Nominal concentrations of tebuthiuron were: 0.0 (control), 600, 1200, 2500, and 5000 ppm. Measured concentrations of tebuthiuron in the diet were: none detected (control), 636, 1210, 2573, and 5113 ppm. Tebuthiuron was found to be evenly distributed and stable (ranging from 99.5 - 103% of initial concentration after one week) in the diet.

One bird in the 1210 ppm test group and one bird in the 5113 ppm exposure level died during the three day period that the birds were fed untreated diet. Both birds were the smallest in their pens and one was the smallest in the study. Both birds gained weight while feeding on the treated diet and no signs of toxicity were noted. It is possible that the stress of handling these small birds, for weighing on day 5, contributed to their deaths. No other mortalities or signs of toxicity were recorded during the study.

Birds in the 2573 and 5113 ppm groups gained significantly less weight as compared with the control group during the 5-day treatment phase. However, there were no significant differences between mean body weight gain values of control and treatment birds during the 3-day basal diet phase (Table 2, attached).

There were no significant differences between the mean food consumption of control birds and any of the treatment group birds during any phase of the study (Table 3, attached).

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

The avian dietary LC₅₀ of tebuthiuron, performed on February 11 to 19, 1988, was found to be greater than 5113 ppm (measured concentration).

A Good Laboratory Practice Statement complying with FIFRA, 40 CFR, Part 160 was signed by the study director. A Quality Assurance Statement, signed by the quality assurance officer, reported that GLP standards were followed except for the fact that the test article characterization was not available prior to the study. However, the characterization was completed and a reference was included in the report.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedures:

SEP Guidelines with the following minor exceptions:

- a) Temperature gradient ranged from 37°C to room temperature (26-28°C). The temperature recommended by the guidelines is 35°C.
- b) Relative humidity ranged from 25% - 46%. Guidelines recommend that humidity not drop below 30%.
- c) No necropsies were performed (recommended, not mandatory).

B. Statistical Analysis: EEB concurs with the study author's finding of a LC₅₀ value of >5113 ppm.

C. Discussion/Results: With an LC₅₀ of >5113 ppm, the test material is considered to be practically non-toxic to the bobwhite quail.

This study is scientifically sound and meets the requirements for an avian dietary study.

D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: N/A
- (3) Repairability: N/A

15. COMPLETION OF ONE-LINER: Yes, May 22, 1991.

TABLE 2. AVERAGE BODY WEIGHTS OF JUVENILE BOBWHITE FED DIETS CONTAINING TEBUTHIURON (EL-103, COMPOUND 75503). STUDY NO. A00188.

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Measured Dietary Concentration (ppm)	Initial Number of Birds	Mean Body Weight \pm SD (g/bird)			Mean Body Weight Gain \pm SD (g/bird)	
		Test Day			Treatment Phase	Basal Diet Phase
		Initial	5	8	(5 Days)	(3 Days)
0.0 (Control)	10	24.3 ± 1.1	36.5 ± 2.6	46.3 ± 4.0	12.2 ± 2.3	9.8 ± 1.9
636	10	24.4 ± 1.0	35.9 ± 3.3	44.4 ± 6.3	11.5 ± 2.7	8.5 ± 3.2
1210	10	24.0 ± 1.6	34.1 ± 2.9	42.9 ^a ± 4.4	10.1 ± 1.9	8.4 ± 2.1
2573	10	24.0 ± 1.5	32.7* ± 3.3	40.3* ± 6.0	8.6* ± 2.4	7.6 ± 2.8
5113	10	23.7 ± 1.2	30.4* ± 2.3	38.7 ^b * ± 7.5	6.7* ± 1.7	8.3 ± 5.8

* Statistically significant difference between this value and the control ($P \leq 0.05$).

^a One bird was found dead on the morning of the first day of the basal diet phase of the study. Mean body weight on day 8 was based on the presence of nine birds instead of 10 birds.

^b One bird was found dead on the morning of the third day of the basal diet phase of the study. However, mean body weight of all 10 birds was included in the calculation of the mean.

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TABLE 3. FOOD CONSUMPTION BY JUVENILE BOBWHITE FED DIETS CONTAINING
TEBUTHIURON (EL-103, COMPOUND 75503). STUDY NO. A00188.

Measured Dietary Concentration (ppm)	Number ^a of Pens	Mean Food Consumption \pm SD (g/bird/day)			
		Treatment Phase		Basal Diet Phase	
		5 Days	% of Control	3 Days	% of Control
0.0 (Control)	2	6.1 ± 0.3	100	8.8 ± 0.1	100
636	2	5.7 ± 0.3	94	7.6 ± 0.1	86
1210	2	5.5 ± 0.2	90	8.0 ^b ± 1.0	81
2573	2	5.6 ± 0.3	93	7.4 ± 1.4	84
5113	2	6.0 ± 1.1	98	8.6 ^c ± 1.2	97

^a Five birds per pen.

^b One bird was found dead on the morning of the first day of the basal diet phase of the study. Food consumption for the basal diet phase was based on the presence of nine birds instead of 10 birds.

^c One bird was found dead on the morning of the third day of the basal diet phase of the study. However, food consumption for the basal diet phase was based on the presence of all 10 birds.